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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,878	11/30/2001	Richard E. Fulton III	216226US-25 CONT	4138

22850 7590 08/29/2003

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EXAMINER
SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
3736	7

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,878	FULTON ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 53-89 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 53-89 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 30 November 2001 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the method steps for marking a biopsy site, and the method steps for identifying tissue that is located within a predetermined distance of a boundary of a biopsy cavity, as claimed in Claims 53-89 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 53-89 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a palpable bioabsorbable marker element that can also be imaged by radiographic or ultrasonic means, does not reasonably provide enablement for dictating the amount of time the bioabsorbable element remains at the site, using CT, MRI, Doppler and a radiation detector to image the marker, specific compounds of collagen and gelatin, coloring the marker, the marker uses a dry powder, sponge or a liquid, and using denatured collagen and renaturing it to provide a base for

the marker. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification of the current invention enables a palpable bioabsorbable marker element that is placed at the site of a biopsy in order to allow the surgeon to more easily relocate the biopsy site. The relocation can be performed through the use of palpation, or through the use of imaging through radiographic and ultrasonic means. The specification also states the marker is made from polylactic acid, polyglycolic acid, lipids, gelatin, hydrogels and other gels, and preferably dehydrated collagen. The specification also enables the marker including a radiopaque marker. See Page 6, lines 23-27; Page 8, lines 24-26; and Page 9, lines 4-8. However, only the summary supports the marker being visually detectable through the use of dyes or coloring agents. See Page 4, lines 28-29.

The specification fails to explicitly disclose the time frame in which the bioabsorbable marker is fully resorbed by the body, for instance the "predetermined time" as claimed in Claims 53, 54, 61 and 62. It is well known in the art that a bioabsorbable element will dissipate at the site over time, but the specification does not disclose: staying at the site for a predetermined amount of time to permit the relocation of the biopsy site; the marker does not interfere with the imaging of the surrounding tissue after a set time; the marker interferes with the imaging of the surrounding tissue during a first time but not after a second time point; and more specifically a time frame

of "2 weeks" as stated in Claim 62, a time frame in which the marker would be resorbed by the body and imaging of the surrounding tissues would not be affected.

The specification also fails to disclose the use of CT, MRI, Doppler, and radiation detection means for locating the marker element, and the material used to make the marker radiopaque. CT is not the same as or similar to a traditional X-ray, nor is Doppler the same as or similar to ultrasound. The specification also fails to disclose the palpable marker consists of at least one bead, and a cross-linked gelatin. The specification also fails to disclose the use a visualization means for the marker element, including a coloring means using dyes and carbon. The specification also fails to disclose the use of a clearance delaying element using an encapsulating material, renatured collagen, renatured gelatin, and/or a crosslinked gelatin. The specification also fails to disclose a marker comprising a dry powder, a sponge, a liquid, collagenous material with radiographically imageable material attached to the marker, and the material comprising ions. The collagen material is not disclosed as renatured collagen or being covalently crosslinked in the specification.

The specification also fails to disclose the method steps in Claims 78 and 79, comprising the steps: obtaining a quantity of denatured collagen; renaturing the collagen; and binding ions to the renatured collagen, or dispersing a radiopaque marker throughout the collagen. The specification also does not disclose the method of Claims 87 and 88, comprising the steps: obtaining a quantity of denatured gelatin; renaturing the gelatin; and binding ions to the renatured gelatin or dispersing a radiopaque marker throughout the renatured gelatin. The specification also fails to disclose the method

steps in Claims 88 and 89, comprising: forming an incision in the patient to permit visualization of the marker material and the boundaries of the biopsy cavity delineated thereby; identifying the tissue that lies within the predetermined distance of the boundary of the biopsy cavity; and excising and removing tissue that lies within the predetermined distance of the boundary of the biopsy cavity. Regarding Claims 88 and 89, the method steps are not clearly set forth in the specification so as to allow one of ordinary skill in the art to perform the claimed method steps.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 62 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 62 recites the limitation "said first time point" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102 & 35 USC § 103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 53-61, 65-71, 88 and 89 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Foerster et al.

Foerster et al disclose a device of marking and defining particular locations in body tissue, and further disclose introducing into the site a detectable marker that remains at the site for a predetermined time; does not interfere with imaging the site at a second time; the marker is detected by using radiographic imaging techniques; the marker is detectable by palpation; the marker comprises at least one bead or a flowable space occupying material; the marker is visually detectable using a dye or a coloring agent; the marker is detectable by using imaging, palpation or visualization; the marker comprises material that is detectable by radiographic, sonographic or magnetic imaging means; introducing into the biopsy cavity a quantity of marker material that is visibly distinguishable form the surrounding tissue to delineate outer boundaries of the biopsy cavity; forming an incision in the patient to permit visualization of the marker material and the boundaries of the biopsy cavity; identifying the tissue that lies within a predetermined distance of the boundary of the biopsy cavity; and excising and removing the tissue that lies within the predetermined distance of the boundary of the biopsy

cavity. See Column 1, lines 19-23; Column 3, lines 26-33; Column 7, lines 24-26 and 41-65; Column 8, lines 62-67; Column 9, lines 1-4; and Column 13, lines 19-26 and 33-36.

Since Foerster et al disclose the use of a biodegradable polymer for a marker and the use of imaging techniques to locate the biopsy site, it would have been obvious to one of ordinary skill in the art to recognize the fact that the marker will not interfere with the imaging of the site once the polymer has fully degraded, since the marker will no longer exist at a second time point. It also would have been obvious to one of ordinary skill in the art to be able to palpate the markers of Foerster et al since the markers are of a different density than the surrounding tissue and would be easily palpated from the surface of the skin. Utilizing a dry powder or a sponge as a marker are also obvious variants of a solid or liquid marker.

10. Claims 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al as applied to claim 53 above, and further in view of Unger et al.

Foerster et al, as discussed above, disclose a bioabsorbable marker that is placed at a biopsy site, but fail to disclose a detectable material that is encapsulated in a clearance delaying material; the detectable material is a lipid; and the clearance delaying material is polylactic or polyglycolic acid.

Unger et al disclose methods for ultrasound imaging involving the use of a contrast agent and further disclose a detectable material that is encapsulated in a clearance delaying material; the detectable material is a lipid; and the clearance delaying material is polylactic or polyglycolic acid. See Column 6, lines 62-67; Column 7, lines 1-4 and 7-

38; Column 21, lines 63-67; Column 22, lines 1-3 and line 40 and lines 47-48; Column 73, lines 35-40.

Since both Foerster et al and Unger et al disclose the use of a biodegradable marker, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the marker structure of Foerster et al to include a lipid filled degradable marker, as per the teachings of Unger et al, since it would provide another means for utilizing CT or MRI as an imaging means to locate the biopsy site. It also would have been obvious to one of ordinary skill in the art to have the marker dissolve within a prescribed time period, since it is well known in the art that polylactic and polyglycolic acid compositions dissolve within a prescribed time period.

11. Claims 72-76 and 80-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al as applied to claim 53 above, and further in view of Ragheb et al.

Foerster et al, as discussed above, disclose a bioabsorbable marker that is placed at a biopsy site, but fail to disclose a collagenous material having radiologically imageable matter attached thereto; the radiologically imageable matter includes ions; the imageable matter comprises a marker; and the marker comprises gelatinous material having radiologically imageable matter combined therewith.

Ragheb et al disclose a silver implantable medical device and further disclose the use of a collagenous material having radiologically imageable matter attached thereto; the radiologically imageable matter includes ions; the imageable matter comprises a

marker; and the marker comprises gelatinous material having radiologically imageable matter combined therewith. See Column 9, lines 1-25.

Since both Foerster et al and Ragheb et al disclose bioabsorbable imageable devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the structure of Foerster et al to include the use of a collagenous material as the base and a coating of a radiopaque substance, as per the teachings of Ragheb et al, since collagen is well known in the art that to be a bioabsorbable material. It also would have been obvious to utilize gelatin, since it is well known in the art to be a derivative of collagen. It also would have been obvious to utilize denatured collagen, renatured collagen, denatured gelatin and renatured gelatin as the material for the marker, since collagen and gelatin are well known in the art to biodegrade in the human body and are obvious variations of collagen and gelatin. It also would have been obvious to utilize crosslinked collagen or crosslinked gelatin since they are variations of collagen and gelatin.

12. Claims 77-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foerster et al as applied to claim 53 above, and further in view of Vogel et al.

Foerster et al, as discussed above, disclose a bioabsorbable marker that is placed at a biopsy site, but fail to disclose using denatured collagen and the imageable matter of the marker comprises ions.

Vogel et al disclose implantable particles and further disclose using denatured collagen and the imageable matter of the marker comprises ions. See Column 6, lines 1-7; and Column 8, lines 18-25.

Since both Foerster et al and Vogel et al disclose bioabsorbable devices, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Foerster et al to include the use of denatured collagen as per the teachings of Vogel et al, since it is well known in the art that denatured collagen is another biodegradable variant of collagen. It also would have been obvious to renature the collagen and bind ions to the renatured collagen or disperse the ions throughout the collagen, since it is well known in the art to utilize chemical variants of biocompatible and biodegradable materials for medical devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (703) 308-3737. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-2701. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

BS

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